

Environmental Protection Agency

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§ 152.46 Notification and non-notification changes to registrations.

(a) *Changes permitted by notification.*

(1) EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished by notification to the Agency, without requiring that the registrant obtain Agency approval. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of modifications permitted by notification and any conditions and procedures for submitting notifications.

(2) A registrant may modify a registration consistent with paragraph (a)(1) of this section and any procedures issued thereunder and distribute or sell the modified product as soon as the Agency has received the notification. Based upon the notification, the Agency may require that the registrant submit an application for amended registration. If it does so, the Agency will notify the registrant and state its reasons for requiring an application for amended registration. Thereafter, if the registrant fails to submit an application the Agency may determine that the product is not in compliance with the requirements of the Act. Notification under this paragraph is considered a report filed under the Act for the purposes of FIFRA section 12(a)(2)(M).

(b) *Changes permitted without notification.* EPA may determine that certain minor modifications to registration having no potential to cause unreasonable adverse effects to the environment may be accomplished without notification to or approval by the Agency. If EPA so determines, it will issue procedures following an opportunity for public comment describing the types of amendments permitted without notification (also known as non-notification). A registrant may distribute or sell a product changed in a manner consistent with such procedures without notification to or approval by the Agency.

(c) *Effect of non-compliance.* Notwithstanding any other provision of this section, if the Agency determines that a product has been modified through notification or without notification in

a manner inconsistent with paragraphs (a) or (b) of this section and any procedures issued thereunder, the Agency may initiate regulatory and/or enforcement action without first providing the registrant with an opportunity to submit an application for amended registration.

[61 FR 33041, June 26, 1996]

§ 152.50 Contents of application.

Each application for registration or amended registration must include the following information, as applicable:

(a) *Application form.* An application form must be completed and submitted to the Agency. Application forms are provided by the Agency, with instructions as to the number of copies required and proper completion.

(b) *Identity of the applicant—(1) Name.* The applicant must identify himself. An applicant not residing in the United States must also designate an agent in accordance with paragraph (b)(3) of this section to act on behalf of the applicant on all registration matters.

(2) *Address of record.* The applicant must provide an address in the United States for correspondence purposes. The U.S. address provided will be considered the applicant's address of record, and EPA will send all correspondence concerning the application and any subsequent registration to that address. It is the responsibility of the applicant and any registrant under § 152.122 to ensure that the Agency has a current and accurate address.

(3) *Authorized agent.* An applicant may designate a person residing in the United States to act as his agent. If an applicant wishes to designate an agent, he must send the Agency a letter stating the name and United States address of his agent. The applicant must notify the Agency if he changes his designated agent. This relationship may be terminated at any time by the applicant by notifying the Agency in writing.

(4) *Company number.* If an applicant has been assigned a company number by the Agency, the application must reference that number.

(c) *Summary of the application.* Each application must include a list of the data submitted with the application, together with a brief description of the

results of the studies. The list of data submitted may be the same as the list required by §158.32 or §161.32, as applicable, of this chapter. The summary must state that it is releasable to the public after registration in accordance with §152.119.

(d) *Identity of the product.* The product for which application is being submitted must be identified. The following information is required:

- (1) The product name;
- (2) The trade name(s) (if different); and
- (3) The EPA Registration Number, if currently registered.

(e) *Draft labeling.* Each application for new registration must be accompanied by five legible copies of draft labeling (typescript or mock-up). Each application for amended registration that proposes to make any changes in the product labeling must be accompanied by five legible copies of draft labeling incorporating the proposed labeling changes. If the proposed labeling change affects only a portion of the labeling, such as the use directions, the applicant may submit five copies of that portion of the label which is the subject of the amendment. Upon request, an applicant for amended registration must submit a complete label to consolidate amendments.

(f) *Registration data requirements.* (1) An applicant must submit materials to demonstrate that he has complied with the FIFRA sec. 3(c)(1)(F) and subpart E of this part with respect to satisfaction of data requirements, to enable the Agency to make the determination required by FIFRA sec. 3(c)(5)(B). Required items are described in subpart E of this part.

(2) An applicant must furnish any data specified in part 158 or part 161 of this chapter, as applicable, of this chapter which are required by the Agency to determine that the product meets the registration standards of FIFRA sec. 3(c)(5) or (7). Each study must comply with:

(i) Section 158.32 of this chapter, with respect to format of data submission.

(ii) Section 158.33 of this chapter, with respect to studies for which a claim of trade secret or confidential business information is made.

(iii) Section 158.34 of this chapter, with respect to flagging for potential adverse effects.

(iv) Section 160.12 of this chapter, with respect to a statement whether studies were conducted in accordance with Good Laboratory Practices of part 160.

(3) An applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under FIFRA sec. 6(a)(2) if the product were registered.

(g) *Certification relating to child-resistant packaging.* If the product meets the criteria for child-resistant packaging, the applicant must submit a certification that the product will be distributed or sold only in child-resistant packaging. Refer to part 157 of this chapter for the criteria and certification requirements.

(h) *Request for classification.* If an applicant wishes to request a classification different from that established by the Agency, he must submit a request for such classification and information supporting the request.

(i) *Statement concerning tolerances.* (1) If the proposed labeling bears instructions for use of the pesticide on food or feed crops, or if the intended use of the pesticide results or may be expected to result, directly or indirectly, in pesticide chemical residues in or on food or feed (including residues of any active ingredient, inert ingredient, metabolite, or degradation product), the applicant must submit a statement indicating whether such residues are authorized by a tolerance or exemption from the requirement of a tolerance issued under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA).

(2) If such residues have not been authorized, the application must be accompanied by a petition for establishment of appropriate tolerances or exemptions from the requirement of a tolerance, in accordance with part 180 of this chapter.

(j) *Fees.* (1) The applicant shall identify the appropriate fee category in the schedule provided for by FIFRA sec. 33,

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and shall submit the fee for that category as prescribed by the latest EPA notice of section 33 fees.

(2) If FIFRA sec. 33 is not in effect, the applicant shall submit any fees required by subpart U of this part, if applicable.

[53 FR 15978, May 4, 1988, as amended at 58 FR 34203, June 23, 1993; 60 FR 32096, June 19, 1995; 72 FR 61027, Oct. 26 2007; 73 FR 75594, Dec. 12, 2008]

§ 152.55 Where to send applications and correspondence.

Applications and correspondence relating to registration should be sent to the Office of Pesticide Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[71 FR 35545, June 21, 2006]

Subpart D [Reserved]

Subpart E—Procedures To Ensure Protection of Data Submitters' Rights

SOURCE: 49 FR 30903, Aug. 1, 1984, unless otherwise noted.

§ 152.80 General.

This subpart E describes the information that an applicant must submit with his application for registration or amended registration to comply (and for the Agency to determine compliance) with the provisions of FIFRA sec. 3(c)(1)(F). This subpart also describes the procedures by which data submitters may challenge registration actions which allegedly failed to comply with these procedures. If the Agency determines that an applicant has failed to comply with the requirements and procedures in this subpart, the application may be denied. If the Agency determines, after registration has been issued, that an applicant failed to comply with these procedures and requirements, the Agency may issue a notice of intent to cancel the product's registration.

[73 FR 75594, Dec. 12, 2008]

§ 152.81 Applicability.

(a) Except as provided in paragraph (b) of this section, §§152.83 through 152.119 apply to:

(1) Each application for registration of a new product;

(2) Each application for an amendment of a registration; and

(3) Each application for reregistration under FIFRA section 3(g).

(b) This subpart E does not apply to:

(1) Applications for registration submitted to States under FIFRA section 24(c);

(2) Applications for experimental use permits under FIFRA section 5;

(3) Applications for emergency exemptions under FIFRA section 18;

(4) Applications to make only one or more of the following types of amendments to existing registrations, unless the Administrator or his designee finds that Agency consideration of scientific data would be necessary in order to approve the amendment under FIFRA section 3(c)(5):

(i) An increase or decrease in the percentage in the product of one or more of its active ingredients or deliberately added inert ingredients;

(ii) A revision of the identity or amount of impurities present in the product;

(iii) The addition or deletion of one or more deliberately added inert ingredients;

(iv) The deletion of one or more active ingredients;

(v) A change in the source of supply of one or more of the active ingredients used in the product, if the new source of the active ingredient is a product which is registered under FIFRA section 3;

(vi) Deletion of approved uses of claims;

(vii) Redesign of the label format involving no substantive changes, express or implied, in the directions for use, claims, representations, or precautionary statements;

(viii) Change in the product name or addition of an additional brand name, if no additional claims, representations, or uses are expressed or implied by the changes;

(ix) Clarification of directions for use;